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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,631	01/16/2003	Charlotte Hauser- Funke	KGB	3848

7590 09/09/2004

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EXAMINER	
KELLY, ROBERT M	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/913,631	HAUSER- FUNKE, CHARLOTTE	
	Examiner	Art Unit	
	Robert M Kelly	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-98* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *50-98* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's agent of record, David Kim, contacted the Examiner on 30 October 2004, wherein it was found that the restriction requirement issued on 1 June 2004 was inadvertently issued on cancelled claims. It was agreed that a new restriction requirement would be issued and the clock would be reset on the period for response to one month from the issuance of the new restriction requirement. This restriction requirement resets the clock for Applicant's response, and the restriction requirement of 1 June 2004 is withdrawn.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 50-70 and 75-79, drawn to a method of using a nucleic acid sequence comprising an HRE and a transgene, which are not functionally linked, and a hormone-hormone receptor complex for preparing a gene transfer agent.

Group II, claim(s) 71-76, drawn to a nucleic acid construct comprising an HRE and a transgene encoding a blood clotting factor, which are not functionally linked, compositions comprising the nucleic acid construct, and methods of making of such compositions.

Group III, claim(s) 83-89, drawn to an agent comprising a nucleic acid construct comprising an HRE and a transgene encoding a blood clotting factor, which are functionally linked, and methods of gene transfer and nucleic acid delivery with such agent.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature shared by Groups I and II is a nucleic acid construct comprising an HRE and a transgene that are not functionally linked. WO 94/28150 to Mader, et al., Filed 18 May 1994, Published 8 December 1994, teaches a plasmid with a glucocorticoid responsive element and an ampicilin resistance transgene, which

are not functionally linked (FIGURE 1) (It is noted that Applicant has supplied this reference in an IDS, and hence it is not supplied in a notice of references cited by the Examiner, but will be considered further during the first examination on the merits). Hence, Mader teaches the special technical feature shared by Groups I and II. Moreover, Group III requires the transgene to be functionally linked with the HRE, and Mader teaches this aspect also (FIGURE 1, insertion site). Furthermore, these structural differences between the three groups yield different functions for these compositions, so they must act through different, no-coextensive mechanisms to exert their effects. For example, Group I requires the non-linked transgene and HRE to be further linked to a hormone-hormone receptor complex, while Group II requires no such further linking to a hormone-hormone receptor complex, and Group III requires the HRE to be functionally linked to the transgene and a hormone-hormone receptor complex. These difference require different considerations, e.g., to determine what is a functional link, what is a non functional link, and how the hormone-hormone receptor interacts in each case. Because of these non-coextensive considerations, the search and examination burden on the examiner would be serious to examine any two groups together. Moreover, because Mader teaches the special technical feature between any two groups, and for the reasons given above, Groups I-III do not relate to a single general inventive concept.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(i) Please choose one of the eleven transgenes, i.e., blood clotting factor, hormone, hormone receptor, growth factor, enzyme, cytokine, lymphokine, inhibitor, drug, vaccine, or antisense, listed in Claims 51 and 67;

(ii) Please choose one of the blood clotting factors, i.e., factor VIII, factor IX, or von Willebrand factor, listed in Claims 53, 68-69, 72, 79, 84, 87-88, and 98; and

(iii) Please choose one of the seven additional sequences, i.e., promoter, enhancer, silencer, origin of replication, integrational, marker, or switch, listed in Claims 59 and 90.

Applicant is required, in reply to this action, to elect a single species for each of the claims that lie within their elected invention to which the claims shall be restricted if no generic

claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 50, 65, 67, 71, 78, 83, 84, and 97.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each of the species have different structure which provides for different functionality, and these structural and functional differences would lead to non-coextensive considerations that would pose a serious burden on the examiner to search any two together. For example, the transgenes include growth factors, which cause certain cell types to grow, while vaccines cause antigenic responses; the additional sequences include integrational sequences, which cause nucleic acids to become integrated into other nucleic acids, while promoters cause the transcription of nucleic acids; and the blood clotting factors act within different steps of the blood clotting cascades to effect the same outcome, but through interaction with different proteins. Hence, in each case, the mechanisms through which these classes act are different, and require different structural and functional considerations that are not coextensive. Because of the non-coextensive search and examination requirements and the fact that searching any two together would pose a serious burden on the Examiner, election of species is proper. However, Applicant is reminded that upon a finding of allowability of any generic claim on the basis of a respective species, examination will be extended to other species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

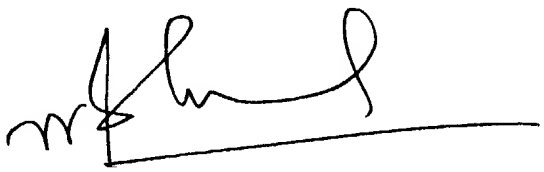
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M Kelly whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER